Atlas Medical

HBsAb

One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma)

A rapid, one step test for the qualitative detection of Antibody to Hepatitis B Surface Antigen (HBsAb or anti-HBs) in serum or plasma.

IVD *For In-Vitro diagnostic and professional use only*

Store at 2-30°C

INTENDED USE

The HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) is a rapid chromatographic immunoassay for the qualitative detection of Antibody to Hepatitis B Surface Antigen in serum or plasma.

INTRODUCTION

Viral hepatitis is a systemic disease primarily involving the liver. Most cases of acute viral hepatitis are caused by Hepatitis A virus, Hepatitis B virus (HBV) or Hepatitis C virus. The complex antigen found on the surface of HBV is called HBsAg. The presence of HBsAg in serum or plasma is an indication of an active Hepatitis B infection, either acute or chronic. The antibody to HBsAg, HBsAb, may not become detectable for 3-6 months after acute infection. It is associated with resolution of the illness. This antibody is recognized as the marker of immunity to HBV. As a result, vaccination against HBV was introduced to control the morbidity and mortality associated with the virus. As part of the World Health Organization (W.H.O) program for the control of Hepatitis B, many people, especially new born infants, receive vaccination. The minimum standard titer of HBsAb is 10 mIU/mL for protective immunity to HBV. Unfortunately, approximately 5-15% of healthy immuno-competent individuals either does not exhibit an antibody response to the existing recombinant vaccination or respond **poorly.**

The HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) is a rapid test to qualitatively detect the presence of HBsAb in serum or plasma specimen. The test utilizes a double antigen sandwich system to detect as low as 10 mIU/mL of HBsAb in serum or plasma.

PRINCIPLE

The HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) is a qualitative, lateral flow immunoassay for the detection of HBsAb in serum or plasma. The membrane is pre-coated with HBsAg on the test line region of the strip. During testing, the serum or plasma specimen reacts with the particle coated with HBsAg. The mixture migrates upward on the membrane chromatographically by capillary action to react with HBsAg on the membrane and generate a colored line. The presence of this colored line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS

MATERIALS PROVIDED

- Test devices(Contain HBsAg particles and HBsAg coated on the membrane).
- Package insert

MATERIALS NEEDED BUT NOT PROVIDED

- Specimen collection container
- Centrifuge (for plasma only)
- Timer

STORAGE AND STABILITY

- The kit can be stored at room temperature or refrigerated (2-30 °C).
- The test device is stable through the expiration date printed on the sealed pouch.
- The test device must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) can be performed using either serum or plasma.
- Separate the serum or plasma from blood as soon as possible to avoid hemolysis. Only clear, non-hemolyzed specimens can be used.
- Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. Specimens may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below - 20°C.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
- If specimens are to be shipped, they should be packed in compliance with federal regulations for the transportation of etiologic agents.

PRECAUTIONS

- For professional *in vitro* diagnostic use only. Do not use after expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Humidity and temperature can adversely affect results.

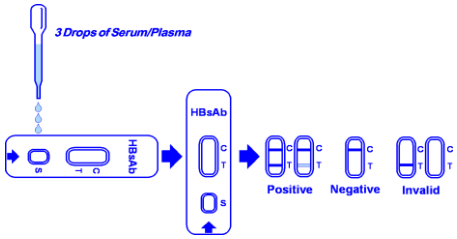
PROCEDURE

Allow test device, serum or plasma specimen, and/or controls to equilibrate to room temperature (15-30°C) prior to testing.

1. Bring the pouch to room temperature before opening it. Remove the test device from the sealed pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test device on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of serum or plasma (approx. 75μl) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration above.
3. Wait for the red line(s) to appear. The result should be read at 15 minutes. It is important that the background is clear before the result is read.

NOTE

A low HBsAb concentration might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 20 minutes.



INTERPRETATION OF RESULTS
(Please refer to the illustration in previous page)

POSITIVE: *
Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T).
NOTE:
The intensity of the red color in the test line region (T) will vary depending on the concentration of HBsAb present in the specimen. Therefore, any shade of red in the test region (T) should be considered positive.
NEGATIVE:
One red line appears in the control region (C). No apparent red or pink line appears in the test region (T).
INVALID:
Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

EXPECTED VALUES
The HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) has been compared with a leading commercial HBsAb RIA test. The correlation between these two systems is over 99%.

QUALITY CONTROL
- Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATION
- The HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) is for *in vitro* diagnostic use only. This test should be used for the detection of HBsAb in serum or plasma specimen.
- The HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) cannot detect less than 10 mIU/mL of HBsAb in specimens.
- As with all diagnostic tests, all results must be considered with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS
Sensitivity

The HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) has been tested with a sensitivity panel ranging from 1 mIU/mL to 40 mIU/mL. The test can detect 10 mIU/mL of HBsAb in 15 minutes.

Specificity

Antigen used for the HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) is highly specific for detecting HBsAb in serum and plasma. The specificity was comparable to RIA.

HBsAb Reference Method

Method		**RIA**		**Total Results**
HBsAb Test Device	Results	Positive	Negative	
	Positive	220	2	222
	Negative	0	150	150
Total Results		220	152	372

Relative Sensitivity: >99.0%
Relative Specificity: 98.7%
Accuracy: 99.5%

Precision
Intra-Assay
Within-run precision has been determined by using 15 replicates of three specimens containing negative, low positive and high positive of HBsAb. The negative and positive values were correctly identified 99% of the time.
Inter-Assay
Between-run precision has been determined by using the same three specimens of negative, low positive and high positive of HBsAb in 15 independent assays. Three different lots of the HBsAb One Step Hepatitis B Surface Antibody Test Device (Serum/Plasma) have been tested over a 3-month period using negative, low positive and high positive specimens. The specimens were correctly identified 99% of the time.

REFERENCES
1. David Siebert. Aust Prescr. 1998;21;72-5
2. Zuckerman JN, Sabin C, Craig FM, Williams A, Zuckerman AJ. Immune response to a new hepatitis B vaccine in healthcare workers who had not responded to standard vaccine: randomised double blind dose-response study. Br Med J 1997; 314:329-33.

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REF	Catalogue Number		Temperature limit
IVD	*In Vitro* diagnostic medical device		Caution
Σ	Contains sufficient for <n> tests and Relative size		Consult instructions for use (IFU)
LOT	Batch code		Manufacturer
	Do not re-use		Use-by date
	Manufacturer fax number		Do not use if package is damaged
	Manufacturer telephone number		Date of Manufacture
	Keep away from sunlight		Keep dry